

## REMARKS

Applicants gratefully acknowledge the Examiner's statement in the Office Action mailed February 8, 2007 that claims 1, 5-14 and 29 are allowed. The Examiner rejected the remaining claims as being unpatentable over various references. Specifically, the Examiner rejected claims 3, 4, 30 and 33 under 35 USC 102(b) as being anticipated by U.S. Publication No. US 2002/0069870 A1 to Farmer, claims 24-27 under 35 USC 103 as being obvious over Farmer, and claims 8 and 28 as being obvious over Farmer in view of U.S. Patent No. 6,279,574 to Richardson. Applicants respectfully disagree for the reasons set forth below.

### **Remarks About The Second Supplemental Information Disclosure Statement:**

Applicants timely mailed a Second Supplemental Information Disclosure Statement (Second Supp. IDS) on October 10, 2006, and made additional comments and a request for consideration thereof in Applicants' Amendment filed November 10, 2007. Applicants have not yet received an initialed Form PTO-1449 from the Examiner.

Accordingly, Applicants respectfully request that the Examiner consider the references submitted with the Second Supp. IDS and initial the Form PTO-1449 enclosed therewith. Should the Examiner have any questions about the Second Supp. IDS, Applicants respectfully invite him to contact the undersigned attorney at his convenience.

### **Remarks About The Prior Art Rejections:**

#### **Claims 3 and 4:**

Amended claim 3 recites "a pressurized metered dose inhaler in flow communication with said second inhalation conduit downstream of said one-way inhalation valve *and upstream of said interior space of said chamber housing,*" with the "second inhalation conduit communicating with said interior space of said chamber housing at said input end, wherein said second inhalation conduit has a

second cross-sectional area defined substantially perpendicular to the longitudinal flow direction at said input end, *wherein said second cross-sectional area is less than said first cross-sectional area.*” Neither of the embodiments (FIGS. 1-4 or FIGS. 5-8) of Farmer disclose or suggest an inhaler in flow communication with the second inhalation conduit *upstream* of the interior space of the holding chamber, wherein the interior space has a greater cross-sectional area than the inhalation conduit at the input end.

Rather, in the first embodiment, as shown in FIG. 3, the medicants from the canister 11 of Farmer pass *directly* into the interior space (Farmer at para. 24), not into a conduit upstream therefrom. The end of the channel 13 is disposed *in the interior space of the reservoir*, not in communication with a second inhalation conduit having a lesser cross-sectional area. Indeed, the channel 13 of Farmer is shaped and directed *away* from the conduit, not in flow communication therewith as recited in claim 3.

Likewise, in the embodiment of FIGS. 5-8, the MDI canister 32 of Farmer delivers medicament directly into the interior space of the reservoir 14, and is not in “flow communication with said *second inhalation conduit . . . upstream* of said , interior space” as recited in claim 3.

Finally, and contrary to the Examiner's assertions, Farmer does not disclose or suggest that the conduit, housing the one-way valve 16 in the embodiment shown in FIG. 1, includes an “oxygen intake line” (Office Action at 2-4, paras. 4 and 5). Rather, Farmer simply discloses that “air” enters the reservoir 14 through the valve 16 (Farmer at Col. 2, paras. 22 and 25). Instead, Farmer discloses only that in a second embodiment of FIGS. 5-8, a T-fitting 40 may be provided for use with “an auxiliary oxygen supply hook-up” (Farmer at para. 27), with that conduit being provided completely separate from the metered dose inhaler connection with the interior space of the reservoir.

Accordingly, because Farmer does not disclose or suggest every element of claim 3, the Examiner's rejections should be withdrawn.

**Claim 32:**

Claim 32 depends from claim 24 and is patentable over Farmer for all of the reasons set forth below. Applicants note, however, that claim 32 further recites “wherein said introducing said medication into said holding chamber comprises introducing said medication into said inhalation conduit *between said holding chamber and said one-way valve.*” As just explained above with respect to claim 3, none of the embodiments in Farmer disclose introducing medication into *a conduit between* the holding chamber and one-way valve, rather the medication is always introduced directly into the holding chamber.

Moreover, the only embodiment of Farmer that discloses a gas source is shown in FIGS. 5-8. In that embodiment, as just noted, the medication is introduced directly into the reservoir 14 of Farmer, rather than into the conduit communicating with the reservoir. Accordingly, Applicants respectfully submit that claim 32 is patentable over Farmer for this additional reason.

**Claim 33:**

As set forth in the prior amendment, claim 33 recites that “a flow path between said interior of said chamber housing and said outlet of said first inhalation conduit through said output end of said chamber housing is *free of any valve structure.*” In the outstanding Office Action, the Examiner has not cited to any portion of Farmer disclosing such a recitation (*see* Office Action at 2-3). Indeed, Farmer discloses just the opposite.

In particular, Farmer discloses that “a one-way proximal diaphragm valve 19 as shown in FIGS. 1 and 2 prevents exhaled gases from entering reservoir 14” (Farmer at para. 24). As shown in FIGS. 1 and 2 of Farmer, the one-way valve 19 is positioned at the interface of the reservoir 14 and the delivery tube 17. Likewise, Farmer discloses a similar valve 19 in the embodiment of FIG. 5. Accordingly, Farmer does not disclose or suggest a flow path between the interior of the chamber housing and the outlet of the first inhalation conduit free of any valve structures, as set forth in claim 33. Since Farmer does not disclose or suggest all of the limitations

of claim 33, and the Examiner has not cited to any portion of Farmer disclosing such a limitation, Applicants respectfully request that the rejection of claim 33 be withdrawn.

**Claims 24-27:**

Claim 24 recites “transmitting oxygen from *a ventilator* through a holding chamber and an inhalation conduit to the patient during an inhalation sequence of a breathing cycle . . . and transmitting said substantial portion of said exhaust gas from said exhaust conduit *to said ventilator* during said exhalation sequence.” In the outstanding Office Action, the Examiner has not addressed Applicants’ prior remarks made in the Amendment filed November 10, 2006 concerning the reasons why one of ordinary skill in the art would not have found it obvious to modify Farmer as suggested by the Examiner.

Instead, the Examiner merely repeats his prior assertions that it would have been obvious to modify Farmer to couple the assembly to a ventilator, relying on a generalized statement in the Background section that refers to a collapsible reservoir being used in a ventilator breathing circuit (Office Action at 4, citing Farmer at para. 4). Nothing in that passage of Farmer, however, refers to the suitability of incorporating the disclosed reservoir of Farmer into such a ventilator circuit, and Farmer in fact teaches against such an application.

In particular, Farmer discloses in one embodiment (FIGS. 1-4) introducing “air” into the reservoir (Farmer at paras. 22 and 25) and, in a second embodiment (FIGS. 5-8), introducing oxygen into the reservoir. In both embodiments, however, the device exhausts gases through valve 21 to the *ambient environment*, not to a ventilator.

Moreover, Farmer discloses the use of an exhaust peep valve 21, which creates resistance during exhalation and prevents the patient from exhaling too quickly (Farmer at paras. 23 and 24). The configuration of the valve 21 which creates resistance during breathing, and which is capped, is not suited for use with a ventilator circuit, and there is no disclosure or suggestion in Farmer that an exhaust

line can be secured to the delivery tube at the end containing the valve 21. Simply put, Farmer does not disclose all of the limitations of claim 24, and there is no suggestion to modify Farmer to incorporate the therapy device into a ventilator circuit.

**Claims 28 and 30:**

As with claim 24, the Examiner has not addressed Applicants' arguments concerning the patentability of claim 28 as set forth in Applicants' Amendment filed November 10, 2006. Instead, the Examiner simply has repeated his assertions made in the prior rejection.

As previously noted in Applicants' prior response, however, claim 28 recites "a WYE connector connecting said second inhalation conduit and said exhaust conduit." Without disputing whether or not Richardson discloses a WYE connector (Office Action at 6), Applicants respectfully submit that there is no suggestion to incorporate such a connector into Farmer. Indeed, Farmer does not disclose or suggest *any connection* between an exhaust conduit and a *second* inhalation conduit coupled to the *input end* of the reservoir as recited in claim 28.

Moreover, as set forth above with respect to claim 24, Farmer does not disclose or suggest connecting the "exhaust conduit" to any other structure, whether a ventilator or a WYE connector or both. Rather, the valve 21 of Farmer is expressly disclosed as venting to the ambient environment, and is not suitable for a ventilator circuit. Accordingly, Applicants respectfully request that claim 28 be passed to allowance on the next Office Action. For the same reasons, Applicants request that claim 30, which recites that "said oxygen intake line and said exhalation conduit are connected to a ventilator," also be passed to allowance.

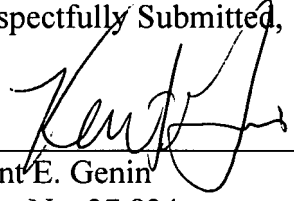
**CONCLUSION:**

If for any reason this application is not considered to be in condition for allowance and an interview would be helpful to resolve any remaining issues, the Examiner is respectfully requested to call the undersigned attorney at (312) 321-7732.

Respectfully Submitted,

Dated: June 8, 2007

By:

  
Kent E. Genin  
Reg. No. 37,834  
Attorney for Applicants

BRINKS HOFER GILSON & LIONE LTD.  
Post Office Box 10395  
Chicago, Illinois 60610  
(312) 321-4200